BIOSENSORS
INTERNATIONAL™

Morges, 24 March 2023

Ref: Validity of EC Certificate N° 2116857CE05

To Whom it may concern,

We hereby inform that Biosensors Europe SA has initiated the transition from MDD 93/42/EC to MDR 2017/745 but the conformity assessment procedure according to MDR has not yet been completed by the Notified Body DEKRA Certification BV.

As of 20th March 2023, the REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15th March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices has entered into force. The amendment extends the MDR transition period as well as the validity of certificates issued in accordance with Directive 93/42/EEC, provided the conditions for the extension of the transition period are met. Consequently, products may be placed on the market or put into service beyond the expiry date of the MDD EC-Certificate, until 31st December 2027 for all class III devices.

Biosensors Europe SA meets the criteria for the MDR transition extension defined in the aforementioned regulation and thus, EC Full Quality Assurance System Certificate Number 2116857CE05, with expiration date of 1st February, 2023, shall remain valid.

Yours sincerely,

Biosensors Europe SA

Orlando Antunes
RA Director EMEA

Biosensors Europe SA
Rue de Lausanne 29
CH - 1110 MORGES
SWITZERLAND
Tel.: +41 (0)21 804 80 00

www.biosensors.com